film is composed so that the film will dissolve within 10 seconds of contact with saliva" (emphasis added). Xu and Ushimaru does not disclose or suggest such a film.

As conceded in the Office Action, Xu does not disclose or suggest a composition that includes an oxidized starch chemically bonded to a cellulose, as recited in claim 1. *See* Office Action, page 6. However, the Office Action asserts that it would have been obvious to modify the composition of Xu by replacing the pregelatinized starch of Xu with an oxidized starch, as employed in Ushimaru. *See* Office Action, page 6.

The Office Action's position relies on its assertion that an oxidized starch is equivalent to a pregelatinized starch, such that a skilled artisan would have readily substituted one for the other. *See* Office Action, page 6. In particular, the Office Action states that "[t]he substitution of on known form of water dispersible starch for another form would have been obvious." *See* Office Action, page 6. However, this assertion completely overlooks the context in which the pregelatinized starch of Xu is used.

Pregelatinization is a process that is employed to improve water-dispersibility of a high molecular weight starch, such as corn or maize starch. Xu discloses using a pregelatinized maize starch to improve stiffness of a film. *See* Xu, column 3, lines 21 to 40. As has been established, e.g., in the Declaration Under 37 C.F.R. §1.132 filed on January 14, 2008, in compositions including a pregelatinized starch and cellulose, chemical bonding does not occur between the pregelatinized starch and cellulose. *See* Declaration, paragraphs 16 to 17. Accordingly, in Xu, stiffness is improved in the absence of a chemical bond between the starch and the cellulose. Because there is no chemical bonding, a pregelatinized having high molecular weight must be employed to improve stiffness. A high molecular weight starch will retain the required water dispersibilily, however, only if the high molecular weight starch is a pregelatinized starch.

As discussed above, Xu explicitly indicates that the pregelatinzed starch is employed to improve the mechanical strength of a film. Accordingly, to retain the character of the film in Xu, one of ordinary skill in the art would not substitute any water dispersible starch for the employed pregelatinized starch – the substituted starch would also have to improve mechanical strength. Oxidized starches are typically low molecular weight starches, due to the oxidation process by which they are formed. One of ordinary skill in the art would not have expected that a low molecular weight starch would be suitable for improving the stiffness of a cellulose polymer film. The only indication that a low molecular weight starch (an oxidized starch) could achieve the objective of good mechanical strength, due to the chemical bond between cellulose and oxidized starch, is found in the present specification. In view of the knowledge of those of ordinary skill in the art at the time of the present invention, to substitute the oxidized starch of Ushimaru for the pregelatinized starch of Xu would be to render the film of Xu unfit for its intended purpose (improved mechanical strength). *See* MPEP §2143.01 (citing *In re Gordon*, 221 USPQ 1125 (Fed. Cir. 1984)) ("If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification").

There is nothing in Xu or Ushimaru that reveals that the effect of the film of claim 1 could be achieved by substituting starches. Xu discloses improving physical properties using high molecular weight starches, because the chemical bond in the film of claim 1 cannot be achieved with the components used to form the film of Xu. Ushimaru fails to recognize that the disclosed oxidized starch could overcome this deficiency.

Moreover, as discussed previously, Xu is directed to "a rapidly dissolvable orally consumable film composition." *See, e.g.,* Xu, Abstract. As discussed previously and conceded in the Office Action, this rapidly dissolvable film composition is formed using a

pregelatinized starch. *See* Xu, column 4, lines 54-63. Ushimaru discloses a preparation including a rapid release portion and a sustained release portion. *See, e.g.,* Ushimaru, Abstract. The oxidized starch identified in the Office Action is employed in the sustained release portion of the preparation of Ushimaru. *See* Ushimaru, claim 2. The Office Action's proposed modification involves replacing a component in a rapidly dissolvable film composition (the pregelatinized starch of Xu) with a component from a sustained release composition, i.e., a composition that is intended to dissolve slowly (the oxidized starch of Ushimaru). One of ordinary skill in the art simply would not have been motivated to do so.

The Office Action asserts that "KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness." *See* Office Action, pages 6 to 7. That is, the Office Action asserts that the mere presence of oxidized starch and cellulose in a sustained release composition in Ushimaru is enough to support the substitution of oxidized starch in any starch and cellulose-containing composition, regardless of context. Applicants submit that this is a severely overbroad reading of *KSR* and its progeny. *See KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). For example, the Board of Patent Appeals and Interferences has stated "[t]he *KSR* Court noted that obviousness cannot be proven merely by showing that the elements of a claimed device were known in the prior art; it must be shown that those of ordinary skill in the art would have had some 'apparent reason to combine the known elements in the fashion claimed.'" *Ex parte Whalen*, 89 USPQ2d 1078, 1084 (Bd. Pat. App. & Int. 2008). The Office Action has simply failed to articulate an apparent reason why one of ordinary skill in the art would have removed the pregelatinized starch from the composition of Xu and used instead the oxidized starch of Ushimaru. A *prima facie* case of obviousness has not been made.

However, even if a *prima facie* case were made, such case is rebutted by the results shown in the present specification and in the Examples of Xu – "[a] *prima facie* case of

obviousness ... is rebuttable by proof that the claimed compounds possess unexpectedly advantageous or superior properties." *See* MPEP §2144.09 (citing *In re Papesch*, 315 F.2d 381 (C.C.P.A. 1963)). The present specification demonstrates that the films according to the present invention dissolve in the mouth in a period of time of less than ten seconds, even when the films have thickness of up to 45 microns. *See, e.g.,* present specification, page 11, lines 25 to 26. By contrast, the films in the Examples of Xu take considerably longer to dissolve. The exemplary films of Xu dissolve in a period of from 30 seconds to 205 seconds. *See* Xu, column 3, lines 6 to 8, TABLE IV. These results are objective evidence of the improvements of film of claim 1 over films as in Xu, and thus these results rebut any suggestion that it would have been obvious to modify the films of Xu in view of the teachings of Ushimaru.

As Xu and Ushimaru fail to disclose or suggest an edible film including at least one oxidized starch that is chemically bound to at least one cellulose compound that is capable of dissolving within 10 seconds of contact with saliva, Xu and Ushimaru fail to disclose or suggest each and every feature of claim 1.

As explained, claim 1 would not have been rendered obvious by Xu and Ushimaru. Claims 4, 8 and 9 depend from claim 1 and, thus, also would not have been rendered obvious Xu and Ushimaru. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Xu, Ushimaru, Hata and Sharik

The Office Action rejects claims 1-6, 8 and 9 under 35 U.S.C. §103(a) over Xu in view of Ushimaru, U.S. Patent No. 4,345,032 to Hata ("Hata") and U.S. Patent No. 5,206,026 to Sharik ("Sharik"). Applicants respectfully traverse the rejection.

For the reasons discussed above, Xu and Ushimaru fail to disclose or suggest the film of claim 1. Hata is cited for its alleged disclosure of lactobacillus strains having the ability to deodorize foul breath. *See* Office Action, page 7. Sharik is cited for its alleged disclosure of films including film-forming polymers such as hydroxyethyl cellulose. *See* Office Action, page 7. However, as Hata and Sharik, like Xu and Ushimaru, fail to disclose or suggest an edible film including at least one oxidized starch that is chemically bound to at least one cellulose compound that is capable of dissolving within 10 seconds of contact with saliva, the combination of references cannot render claim 1 obvious.

As explained, claim 1 would not have been rendered obvious by Xu, Ushimaru, Hata and Sharik. Claims 2-6, 8 and 9 depend from claim 1 and, thus, also would not have been rendered obvious by Xu, Ushimaru, Hata and Sharik. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

For the foregoing reasons, Applicants submit that claims 1-9 are in condition for allowance. Prompt reconsideration and allowance are respectfully requested.

Respectfully submitted,

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